

Docket No.: 04266/100M619-US3

1. LW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Amedeo LEONARDI, et al.

Group Art Unit: 1614 ✓

Examiner: TBA

For: LERCANIDIPINE/ARB/DIURETIC THERAPEUTIC COMBINATION

April 15, 2005

INFORMATION DISCLOSURE STATEMENT

**Mailstop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.).

- ☒ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant identifies these documents by attaching hereto copies of the forms PTO-892 and PTO/SB08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these

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documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

[X] 3. Document(s) 18 and 19 are not in the English language. In accordance with 1.98(c),

Applicant states:

- ☒ [X] An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☐ [] A concise explanation of the relevance of document(s) _____ is found in the attached search report (see MPEP § 609 A(3)x).
- ☐ [] A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ [] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ [] A concise explanation of document(s) _____ and _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

[X] 5. Other information being provided for the examiner's consideration follows:

An International Search Report, dated August 10, 2004, which issued during the prosecution of International Application No. PCT/EP2004/002000 which is a counterpart to the present application.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Patent Application Serial No _____, filed _____.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

Michael Beente

Mitchell Bernstein, Ph.D.
Registration No. 46,550
Agent for Applicants

April 15, 2005

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Application No. (if known): 10/791,148 ✓

Attorney Docket No.: 04266/100M619-US3 ✓

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Lillian Garcia

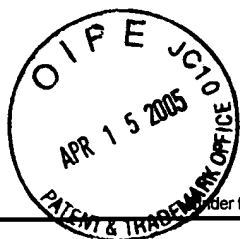
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Information Disclosure Statement (4 pages)
International Search Report - PCT/EP2004/002000 (5 pages)
Form PTO/SB/08a/b (3 pages) and 30 References
Return Receipt Postcard



PTO/SB/08a/b (08-03)
 Approved for use through 07/31/2006. OMB 0651-0031
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/791,148
				Filing Date	March 1, 2004
				First Named Inventor	Amedeo Leonardi
				Art Unit	1614
				Examiner Name	TBA
Sheet	1	of	2	Attorney Docket Number	04266/100M619-US3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A	6,517,871	02/11/2003	Venkatesh et al.	
	B	6,395,728	05/28/2002	Webb et al.	
	C	6,204,281	03/20/2001	Webb et al.	
	D	6,071,939	06/06/2000	Gaviraghi et al.	
	E	2004/0254176	12/16/2004	Grigorieff et al.	
	F	2004/0002529	01/01/2004	Sada et al.	
	G	2003/0181500	09/25/2003	Lee et al.	
	H	2003/0175344	09/18/2003	Wald et al.	
	I	2003/0008904	01/09/2003	Buch, Jan	
	J	2002/0098241	07/25/2002	Venkatesh, Gopadi M.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	1	WO 03/097045	11/27/2003	Novartis Pharma GMBH		
	2	WO 03/014084	02/20/2003	Recordati Ireland Limited		
	3	WO 02/43807	06/06/2002	Novartis AG		
	4	WO 02/35046	05/02/2002	EGHOLM, et al.		
	5	WO 02/06253	01/24/2002	Norvartis-Erfindungen Verwaltungsgesellschaft MBH		
	6	WO 01/13900	03/01/2001	Medicure Inc.		
	7	WO 00/27397	05/18/2000	Glaxo Group Limited, et al.		
	8	WO 00/27396	05/18/2000	Glaxo Group Limited, et al.		
	9	WO 00/02543	01/20/2000	Norvartis-Erfindungen Verwaltungsgesellschaft MBH		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	10	Aranda, F.J. et al. (2000) "Therapeutic Efficacy and Tolerability of Lercanidipine versus Candesartan, Alone or in Combination, in Mild-Moderate Essential Hypertensives," <i>Journal of Hypertension</i> 18(2): S152 (abstract)	
	11	Epstein, MD, Murray (2001) "Lercanidipine - A Novel Dihydropyridine Calcium-Channel Blocker," <i>Heart Disease</i> 3: 398-407	
Examiner Signature			Date Considered

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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Sheet	2	of	2	Attorney Docket Number	04266/100M619-US3

12	Gasser et al. (1999) "Lercanidipine, a new third generation Ca-antagonist in the treatment of hypertension", <i>J Clin Basic Cardiol</i> , 2:169-174
13	Grandi et al. (2002) "Aldosterone Antagonist Improves Diastolic Function in Essential Hypertension", <i>Hypertension</i> , 40:647-652
14	Kurashivili, Ramaz B. et al. "24-Hour Monitoring in Hypertensive Patients with Type II Diabetes Mellitus: Combination Therapy with Lacidipine and Irbesartan (undated abstract)
15	Mancia et al. (1998) "Clinical Advantages of Lipophilic Dihydropyridines", <i>Blood Pressure</i> , 7(suppl 2):23-26
16	Mancia and Grassi (1994) "Combination treatment of hypertension", <i>High Blood Pressure</i> , 3 (suppl to No. 4): 5-7
17	Martell et al. (2003) "Association of Lercanidipine Plus Enalapril to Control Blood Pressure," presented at the American Society of Hypertension, May 14-17, 2003, New York, NY (abstract)
18	Martell et al. (2002) "Asociaciones Terapéuticas en El Control de la Presión Arterial," Poster and Abstract presented at the 7 th Reunión Nacional Sociedad Española de Hipertensión Liga Española para la Lucha contra la Hipertensión Arterial, <i>Hipertensión</i> 19(2), Abstract 61T
19	Martell et al. (2002) "Asociaciones Farmacologicas en Hipertensos con Factores de Riesgo Cardiovascular," Poster and Abstract presented at the 7 th Reunión Nacional Sociedad Española de Hipertensión Liga Española para la Lucha contra la Hipertensión Arterial, <i>Hipertensión</i> 19(2), Abstract 69T
20	McClellan and Jarvis (2000) "Lercanidipine: A Review of its Use in Hypertension", <i>Drugs</i> , 60:1123-1140
21	Messerli, MD, Franz (2002) "Vasodilatory Edema: A Common Side Effect of Antihypertensive Therapy," <i>Current Cardiology Reports</i> 4: 479-482
22	Morgan, Trefor et al. (2002) "A Comparison of Candesartan, Felodipine, and Their Combination in the Treatment of Elderly Patients with Systolic Hypertension," <i>American Journal of Hypertension</i> 15(6): 544-549
23	Omboni and Zanchetti (1998) "Antihypertensive efficacy of lercanidipine at 2.5, 5 and 10mg in mild to moderate essential hypertensives assessed by clinic and ambulatory blood pressure measurements", <i>J Hypertens</i> , 16:1831-1838
24	Ramsay et al. (1999) "Guidelines for management of hypertension: report of the third working party of the British Hypertension Society", <i>J of Human Hypertension</i> , 13:569-592
25	Recordati et al. (2000) "Effects of a reversible 'nephrectomy' on renal sympathetic activity and blood pressure in the rat: evidence for an acute angiotensin-mediated hypertension", <i>Journal of Hypertension</i> , 18:1277-1287
26	Rengo and Romis (1997) "Activity of Lercanidipine in Double-Blind Comparison with Nitrendipine in Combination Treatment of Patients with Resistant Essential Hypertension", <i>J of Cardiovascular Pharmacology</i> , 29(suppl 2):S54-S58
27	Ruzicka, MD, Marcel et al. (2002) "Combination therapy as first-line treatment of arterial hypertension," <i>Can. J. Cardiol.</i> 18(12): 1317-1327
28	Sarafidis et al. (2004) "The Effect of Telmisartan and Lercanidipine on Blood Pressure and Insulin Resistance in Hypertensive Patients," <i>Review of Clinical Pharmacology and Pharmacokinetics, International Edition</i> 18:60-66

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	29	van Zwieten (2000) "The influence of antihypertensive drug treatment on the prevention and regression of left ventricular hypertrophy", <i>Cardiovascular Research</i> , 45:82-91	
	30	Weir AJH (1998) "The Rationale for Combination Versus Single-Entity Therapy in Hypertension", <i>American Journal of Hypertension</i> , 11:163S-169S	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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